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| 10/081,170      | 02/22/2002  | Yoshihiro Kawaoka    | 800.029US1          | 8446             |

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MINNEAPOLIS, MN 55402

EXAMINER

DEVI, SARVAMANGALA J N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/081,170

Applicant(s)

KAWAOKA, YOSHIHIRO

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-14 and 16-36 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 12-14 and 16-31 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-11 and 32-36 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **RESPONSE TO APPLICANT'S AMENDMENT**

### **Applicant's Amendment**

- 1) Acknowledgment is made of Applicant's amendment filed 01/26/06 in response to the non-final Office Action mailed 08/24/05.

### **Status of Claims**

- 2) Claim 1 has been amended via the amendment filed 01/26/06.  
Claims 1, 3-6, 8-14 and 16-36 are pending.  
Claims 1, 3-6, 8-11 and 32-36 are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Withdrawn**

- 5) The rejection of claims 1, 3, 4, 8, 32 and 34-36 made in paragraph 14 of the Office Action mailed 02/08/05 and maintained in paragraph 13 of the Office Action mailed 08/24/05 under 35 U.S.C. § 102(b) as being anticipated by Martin *et al.* (*Virology* 241: 101-111, 1998, already of record) or Brandli *et al.* (*J. Biol. Chem.* 263: 16283-16290, 1988, already of record) as evidenced by Doyle *et al.* (US 20040132164) and Ito *et al.* (*J. Virol.* 71: 3357-3362, 1997), is withdrawn upon further consideration.
- 6) The rejection of claim 1 made in paragraph 14(a) of the Office Action mailed 08/24/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the claim.
- 7) The rejection of claims 3-6, 8-11 and 32-35 made in paragraph 14(b) of the Office Action mailed 08/24/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicant's amendment to the base claim.

8) The rejection of claims 1, 3, 9, 33 and 36 made in paragraph 15 of the Office Action mailed 08/24/05 under 35 U.S.C. § 102(b) as being anticipated by Tazikawa *et al.* (JP 407203958A) as evidenced by Doyle *et al.* (US 20040132164, already of record), is withdrawn.

### **New Rejection(s) Based on Applicant's Amendment**

The new rejection(s) set forth below are necessitated by Applicant's amendment to the claim(s).

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

9) Claims 1, 3-6, 8-11 and 32-35 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 1 is vague, indefinite or confusing in the limitation: 'mutant ... cell comprising decreased levels of N-acetylneuraminic acid and/or decreased levels of N-glycolylneuraminic acid .... wherein the mutant cell is selected for resistance to growth inhibition by a lectin which binds terminal sialic acid containing residues in sialic acid-containing host cell receptor'. Does it mean that the mutant cell comprising decreased levels of both N-acetylneuraminic acid *and* N-glycolylneuraminic acid of any linkage is selected for resistance to growth inhibition by 'a' single lectin?

(b) Claims 3-6, 8-11 and 32-35, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C. § 102**

10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11) Claims 1, 3, 4, 8-10 and 32-36 are rejected under 35 U.S.C. § 102(a) as being anticipated by Takeda *et al.* (*Mol. Biol. Cell.* 11: 3219-3232, September 2000) as evidenced by Ito *et al.* (*J. Virol.* 71: 3357-3362, April 1997, already of record).

It is noted that the MDCK cell line is recognized in the art as a standard cell line used in studies of influenza viruses and viral receptor-based analyses. See line 17 on page 24 of the

specification.

Takeda *et al.* taught isolated, sialidase-treated MDCK transfectant (i.e., mutant) cells having the majority of the sialic acid residues removed. The sialidase-treated mutant MDCK cells comprise decreased levels of sialic acid compared to parental MDCK cells. See abstract; Table 2; and page 3225, left column. The prior art MDCK mutant cells are therefore expected to contain decreased levels of terminal sialic acid-containing host cell receptors for influenza virus relative to a corresponding wild-type cell that supports efficient influenza virus replication and are expected to be resistant to growth inhibition by *Maackia amurensis* lectin or *Sambucus nigra* lectin in light of what is known in the art. For instance, Ito *et al.* taught that *Maackia amurensis* agglutinin (MAA) is specific for the sialic acid alpha-2,3Gal linkage and that *Sambucus nigra* agglutinin is specific for the sialic acid alpha-2,6Gal-N-acetylgalactosamine (see paragraph bridging left and right columns on page 3358). Most importantly, Ito *et al.* expressly taught that MDCK cells contain both of these linkages (see abstract). Since the prior art mutant cell meets the structure of the mutant cell claimed in the instant claim 1, the ability to allow efficient replication of influenza virus with reduced sialidase activity is viewed as an inherent property inseparable from the prior art mutant cell.

The limitations 'wherein the mutant cell is selected for ..... molecules' in claim 1 represent process limitations. When claims are drawn to a product-by-process, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps.

MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicant has not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicant has not shown the underlying structure of the prior art mutant MDCK cell differs from that of the instantly claimed mutant cell.

Claims 1, 3, 4, 8-10 and 32-36 are anticipated by Takeda *et al.* The reference of Ito *et al.* is **not** used as a secondary reference in combination with Takeda *et al.*, but rather is used to show that

every element of the claimed subject matter is disclosed by Takeda *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

### Remarks

**12)** Claims 1, 3-6, 8-11 and 32-36 stand rejected.

**13)** Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**14)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300.

**15)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**16)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the

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Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

April, 2006



S. DEVI, PH.D.  
PRIMARY EXAMINER